NOV 1 6 2000

510(k) Summary

K003261

Introduction

According to the requirements established in the Food and Drug Administration's guidance document entitled "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(800) 428-5074 ext. 3723

Contact Person: Priscilla A. Hamill

Date Prepared: October 16, 2000

2) Device name

Proprietary name: Creatinine plus reagent
Common name: Creatinine reagent
Classification name: Enzymatic Method, Creatinine

3) Predicate device

We claim substantial equivalence to the currently marketed Creatinine plus application on the Roche/Hitachi family of analyzers (K953239).

510(k) Summary CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, Continued

4) Device Description	The Roche Creatinine plus test consists of a cassette containing reagents for the quantitative determination of creatinine on the Integra anazlyers. The test employs the enzymatic method, and is based on the determination of hydrogen peroxide after conversion of creatinine with the aid of creatininase, creatinase, and sarcosine oxidase. Hydrogen peroxide reacts with 4-aminophenazone and HTIB to form a quinone imine chromogen.
5) Intended use	The COBAS INTEGRA Creatinine plus is intended for use on COBAS INTEGRA analyzers for the quantitative determination of the creatinine concentration in serum, plasma, and urine.
6.) Substantial equivalence	The proposed device is the Creatinine plus reagent packaged for and applied to the COBAS Integra family of analyzers. The COBAS Integra family application described in this submission is, in our opinion, substantially equivalent to the predicate device.
7.) Comparison to predicate device	The COBAS Integra application of the Creatinine plus assays has the same intended use and indication for use, the same scientific principle, the same formulation and similar application parameters as the predicate device, the Creatinine plus assay as applied to the Roche/Hitachi family of analyzers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 16 2000

Ms. Priscilla A. Hamill
Regulatory Affairs Consultant
Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, Indiana 46250-0457

Re: K003261
Trade Name: Creatinine Plus Reagent Application
Regulatory Class: II
Product Code: JFY
Dated: October 16, 2000
Received: October 18, 2000

Dear Ms. Hamill:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):
Device Name: **Creatinine plus**

Indications for Use:
Creatinine assays are conducted for diagnostic purposes, for therapeutic monitoring of acute and chronic renal diseases, and for monitoring kidney dialysis. The urinary creatinine concentration can also be used as a reference parameter for analyte excretion (albumin α-amylase).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003261

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)